

**REMARKS**

Claims 1-31 are pending in this application. By this Amendment, claims 1-13, 15-18, and 22-31 are amended. Support for the amendments to the claims may be found, for example, in the specification at page 1, line 25 to page 2, line 3. No new matter is added.

**I. Response to Restriction and Election Requirement**

In reply to the March 31, 2009 Restriction and Election of Species Requirement, Applicant provisionally elects Group I, claims 1-9 and elect the following species:

- HER-2 as the gene;
- SEQ ID NO:12 as the single detection probe;
- SEQ ID NOs:7 and 8 as the two primers for the elected gene; and
- SEQ ID NOs:27 and 28 as the two primers for the housekeeping gene;

with traverse. At least claims 1-9 read on the elected species. Claims 1-9 are generic.

**A. Standard**

National stage applications filed under 35 U.S.C. §371 are subject to unity of invention practice as set forth in PCT Rule 13, and are not subject to U.S. restriction practice. See MPEP §1893.03(d). PCT Rule 13.1 provides that an "international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." PCT Rule 13.2 states:

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

A lack of unity of invention may be apparent "*a priori*," that is, before considering the claims in relation to any prior art, or may only become apparent "*a posteriori*," that is, after

taking the prior art into consideration. *See* MPEP §1850(II), quoting *International Search and Preliminary Examination Guidelines* ("ISPE") 10.03. Lack of *a priori* unity of invention only exists if there is no subject matter common to all claims. *Id.* If *a priori* unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established *a posteriori* by showing that the common subject matter does not define a contribution over the prior art. *Id.*

Furthermore, unity of invention only needs to be determined in the first place between independent claims, and not the dependent claims, as stated in ISPE 10.06:

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of one or more other claims and contains a reference, preferably at the beginning, to the other claim or claims and then states the additional features claimed (Rule 6.4).

*See also* MPEP §1850(II). ISPE 10.07 further provides:

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

*See also* MPEP §1850(II).

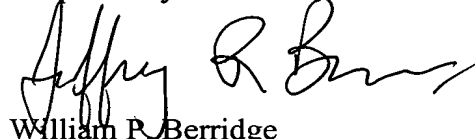
## **B. Application of the Standard**

The Office Action asserts that Groups I and II do not relate to a single general inventive concept because they lack the same of corresponding special technical features. Specifically, the Office Action asserts that U.S. Patent No. 5,474,796 to Brennan teaches the detection probe of claim 15. Without conceding the propriety of the restriction requirement, claims 1, 2, 9, 10, 12, and 15 are amended to recite "15 nucleotide motifs" instead of "10 nucleotide motifs." Accordingly, Brennan is no longer applicable to the present claims.

Additionally, the Office Action has applied the incorrect standard in requiring an election between species. Although unity of invention practice under PCT Rule 13 recognizes that alternate forms of an invention may be present in separate independent claims, or in a single claim, restriction between distinct embodiments of a single claim may only be required if there is a lack of unity of invention in that claim, or, in other words, the distinct embodiments share no common subject matter that defines a contribution over the prior art. *See* ISPE 10.09; MPEP §1850(II). The "patentably distinct species" standard, as applied under U.S. restriction practice, is not applicable to the current claims. Furthermore, the Office Action fails to establish that the "patentably distinct species" lack *a posteriori* unity of invention. Accordingly, the election of species requirement is improper and must be withdrawn.

Thus, withdrawal of the Restriction and Election of Species Requirement is respectfully requested.

Respectfully submitted,



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